DEPARTMENT OF STATE CONGRESSIONAL CORRESPONDENCE TASKER

IPS CONTROL#H2011 0414=008 ACTION BUREAU: GAC

DATE: 4/14/11

IPS:

X SUBSTANTIVE CONSTITUENT

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BUREAU:

BUREAU ACTION REQUESTED: RESPOND TO CCU **2** DAYS FROM:_____

_____REPLY FOR SIGNATURE BY **Joseph E. Macmanus**, ACTING ASSISTANT SECRETARY, LEGISLATIVE AFFAIRS

_____ADDRESS ENVELOPE TO DISTRICT OFFICE

_____DIRECT REPLY TO CONSTITUENT BY OFFICE DIRECTOR WITH COPY TO CONGRESSIONAL OFFICE. PHONE 7-1608 WHEN COMPLETED

_____FYI ONLY/NO RESPONSE NECESSARY

_____REPLY FOR SIGNATURE DIRECTLY BY BUREAU

_____OTHER ACTION:

FOR GUIDANACE/INFORMATION ON FORMATTING CONGRESSIONALS SEE:
http://diplopedia.state.gov/index.php?title=Bureau of Legislative Affairs Reference Documents#Yellow Border

Due Date 4/19/11

****BUREAUS MUST MAKE TRANSFERS OF ACTION DIRECTLY WITH RECEIVING BUREAU'S FRONT OFFICE. The CCU has a listing of contacts. PLEASE NOTIFY CCU 7-1608 OF ALL TRANSFERS OF ACTION****

FROM: Joseph E. Macmanus (H)

APR 14 2011

Recommendation

_____ For the Secretary's signature to the ____bureau

__✓__ Tasked to the GAC bureau for signature by Joseph E. Macmanus Acting Assistant Secretary

_____ Provide copy of H signed response

COMMENTS:

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

April 13, 2011

Secretary of State Hillary Rodham Clinton
U.S. Department of State
2201 C Street N.W.
Washington, DC 20520

Dear Secretary Clinton:

In has been brought to my attention that Global Fund dollars have been used to procure generic drugs at unnecessary costs in recipient countries while brand drugs remain available at a lower cost. Further, it appears that officials of the Global Fund are promoting compulsory licenses and verbally conditioning these licenses for the Global Fund grants. Information related to the procurement of high cost generics is posted on the Global Fund's website and I have attached a compilation of the data for your review. Slides used by the Global Fund to brief officials on how to promote compulsory licenses have also been attached.

In a critical time for global health with caps placed on providing treatment to new patients in a number of the President's Emergency Plan for AIDS Relief (PEPFAR) countries it is extremely concerning that U.S. funded programs, such as the Global Fund, are making inefficient and unnecessarily costly procurement decisions that come with dire consequences. Unfortunately, officials of the Global Fund are promoting the use of generics without regard to the health and financial consequences it may have on the individuals benefiting from the program. It is unclear how often this has occurred, but unfortunately, these actions have likely cost millions of dollars of excessive waste and abuse of the program.

The original PEPFAR legislation was carefully written to ensure access to inexpensive life saving medication for recipient countries. The purpose of the Food and Drug Administration (FDA) Tentative Approval process for Anti-retrovirals (ARV) was to allow the program to purchase generic drugs for use only in PEPFAR countries and has been a great success. It was assumed that access to generic versions of the innovator drugs that were still under patent would provide access to lower cost medications, but the program does not require the purchase of generics. The statute is clear that treatment funds should be used in the most efficient manner. It is quite concerning that the Global Fund determines procurement policies based on the producer of the drug rather than the quality or price.

In addition, the FDA Tentative Approval process was established in partnership with innovator companies and should never be exploited. By advocating for developing countries to disregard the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) through issuing compulsory licenses to gain access to Global Fund grants, we are abusing the system. Access to these products is vital to our success in fighting the war on HIV/AIDS and actions inconsistent with patent law such as these will only hinder our ability to work in

partnership with the companies that have provided the intellectual property rights to develop generic versions of their products. This is a humanitarian effort that requires all parties – government, non-governmental organizations, and industry – to work together towards the same goal.

I would appreciate a thorough review of the attached materials. I am requesting that you work in coordination with the Global Fund to explain the decision to purchase generic drugs at a higher cost, when brand drugs were available at a lower price. Further, the Department of State and the Global Fund should develop a specific plan of action to rectify this discrepancy for future procurement. I also request that you provide an immediate plan of action prohibiting any seminars or working groups by the Global Fund related to educating, training and advocating for countries to issue compulsory licenses.

ARV treatment and other medical care are a critical component to our success in the war against HIV/AIDS, both at home and globally. In these difficult budgetary times it is imperative that every dollar is spent in an effective and efficient manner and based on the quality and cost efficiencies of the product. Individuals around the world are depending on access to these treatments. Implementers must do everything in their power to maximize the impact of the Global Fund grants, in order to treat the greatest number of individuals possible. I look forward to your timely and thorough response to these urgent matters.

Sincerely,

Orrin G. Hatch
Ranking Member
Senate Committee on Finance

Country	Drug Name	Strength	Quantity per Package	Total Number Smallest Units	Unit Price	Total Price Paid	Annual Treatment Cost per Patient	Dosage Form	Therapeutic Category	Abbott Cost	Manufacturer	Country of Manufacture	Date of Order	Grant Number	Source Name
Burkina Faso	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	90	99,360	$0.25	**$24,706**	545	Oral Solid (tablets/capsules)	Antiretroviral		Cipla Ltd.	India	09.12.2005	BUR-202-G02-H-00	Global Fund
	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg		99,360	$0.25	**$24,706**	547.5			**$22,654**	Abbott		09.12.2005		
Equatorial Guinea	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	180	11,520	$0.23	**$2,630**	500	Oral Solid (tablets/capsules)	Antiretroviral		Cipla Ltd.	South Africa	22.05.2007	GNQ-405-G01-H	Global Fund
	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg		5,760	$0.46	**$2,630**	1,007.40			**$1,313**	Abbott		22.05.2007		
Eritrea	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	90	18,000	$0.92	**$16,486**	2,006.00	Oral Solid (tablets/capsules)	Antiretroviral		Hetero Drugs Ltd.	India	01.12.2006	ERT-304-G02-H	Global Fund
	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg		18,000	$0.92	**$16,486**	2,014.80			**$4,104**	Abbott		01.12.2006		
Gambia	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	90	45,000	$0.71	**$31,750**	1,546.00	Oral Solid (tablets/capsules)	Antiretroviral		Hetero Drugs Ltd.	India	02.08.2006	GMB-304-G01-H	Global Fund
	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg		45,000	$0.71	**$31,750**	1,554.90			**$10,260**	Abbott		02.08.2006		
Lao PDF	No information on this purchase														
	Lopinavir (LPV) + Ritonavir (RTV)	50 mg + 200 mg		3,480	$1.29	**$4,501**	1,883.40			**$1,190**	Abbott		10.04.2008		
Malawi	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	90	137,700	$0.46	**$62,883**	1,001.00	Oral Solid (tablets/capsules)	Antiretroviral		Cipla Ltd.	India	23.10.2006	MLW-102-G01-H-00	Global Fund
	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg		137,700	$0.46	**$62,883**	1,007.40			**$31,396**	Abbott		23.10.2006		
Malawi	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	90	291,600	$0.46	**$133,164**	1,001.00	Oral Solid (tablets/capsules)	Antiretroviral		Cipla Ltd.	India	10.10.2005	MLW-102-G01-H-00	Global Fund
	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg		291,600	$0.46	**$133,164**	1,007.40			**$16,416**	Abbott		10.10.2005		
Sierra Leone	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg	180	72,000	$1.00	**$72,320**	2,200.00	Oral Solid (tablets/capsules)	Antiretroviral		Cipla Ltd.	India	31.10.2005	SLE-405-G02-H	Global Fund
	Lopinavir (LPV) + Ritonavir (RTV)	133.3 mg + 33.3 mg		72,000	$1.00	**$72,320**	2,190.00			**$16,416**	Abbott		31.10.2005		

Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Global Fund Experience:
access to patent information and impact on procurement of medicines

February 2011

Dr. Sophie Logez
Manager, QADM Team, Pharmaceutical Unit

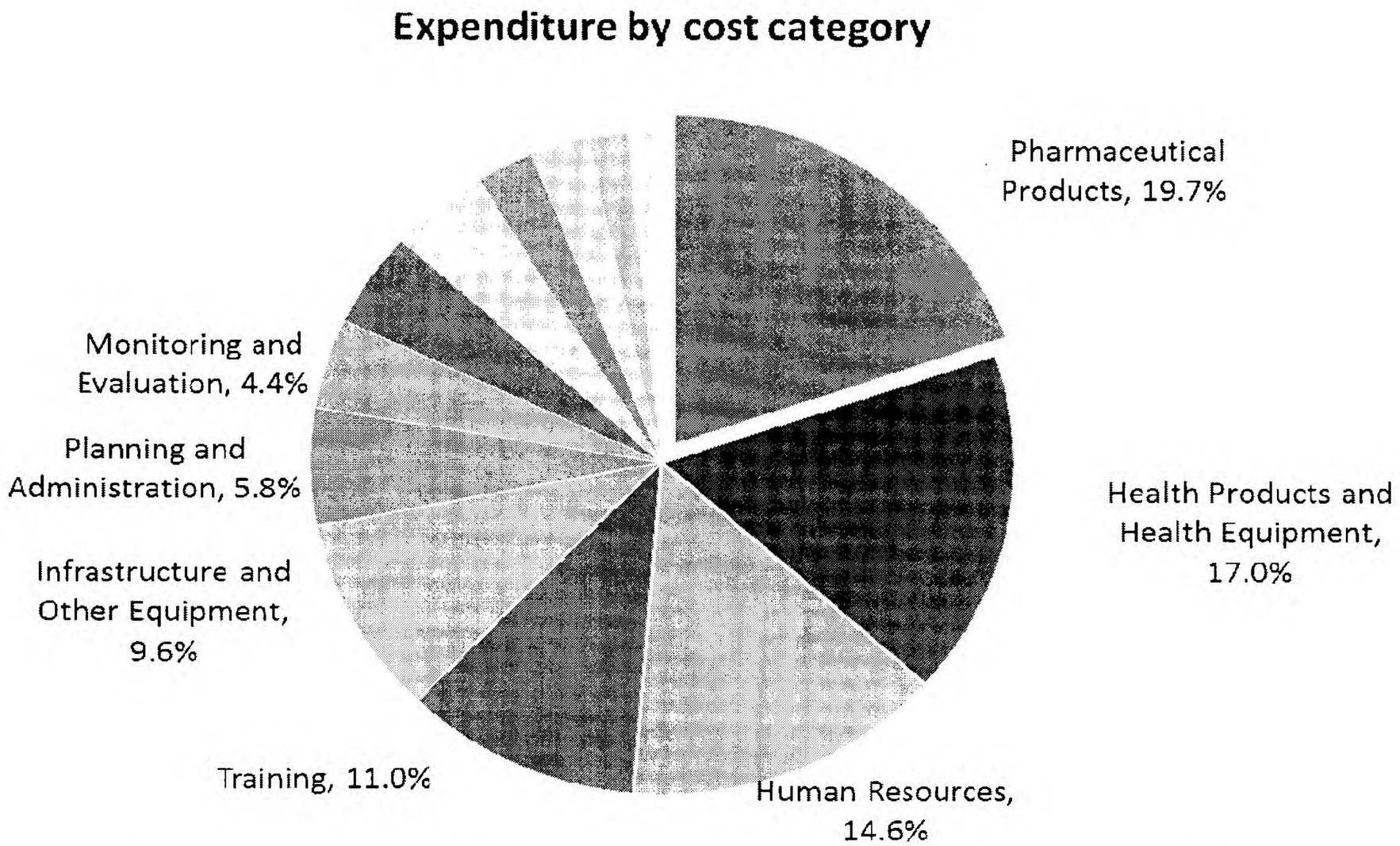
Carmen Perez Casas
Senior TO, Pharmaceutical Management Unit

El Fondo Mundial · 全球基金 · The Global Fund · Le Fonds mondial · Глобальный фонд · الصندوق العالمي

Content

- Global Fund :
  - Procurement and Supply Management Policies
  - Price differences among grantees
- General information from experience:
  - Management of patent issues in procurement cycle
  - Availability and quality of information
- Searching for solutions to facilitate procurement:
  - What information could be useful
  - Sustainable and simplified approaches

Use of the Global Fund Grant Funding

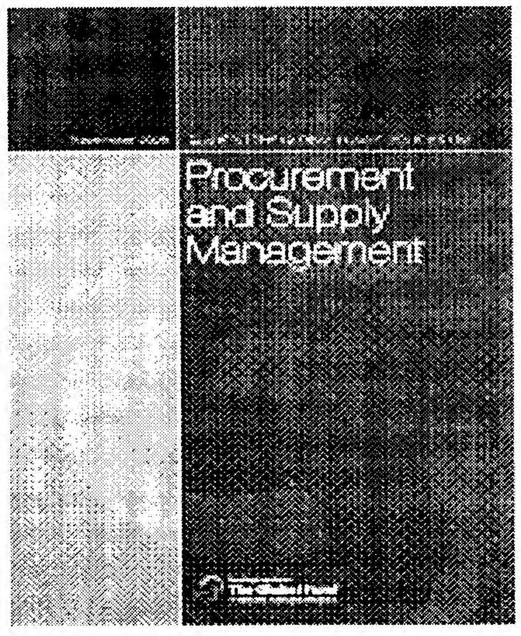


37% percent of funds are used for medicines and health products procurement

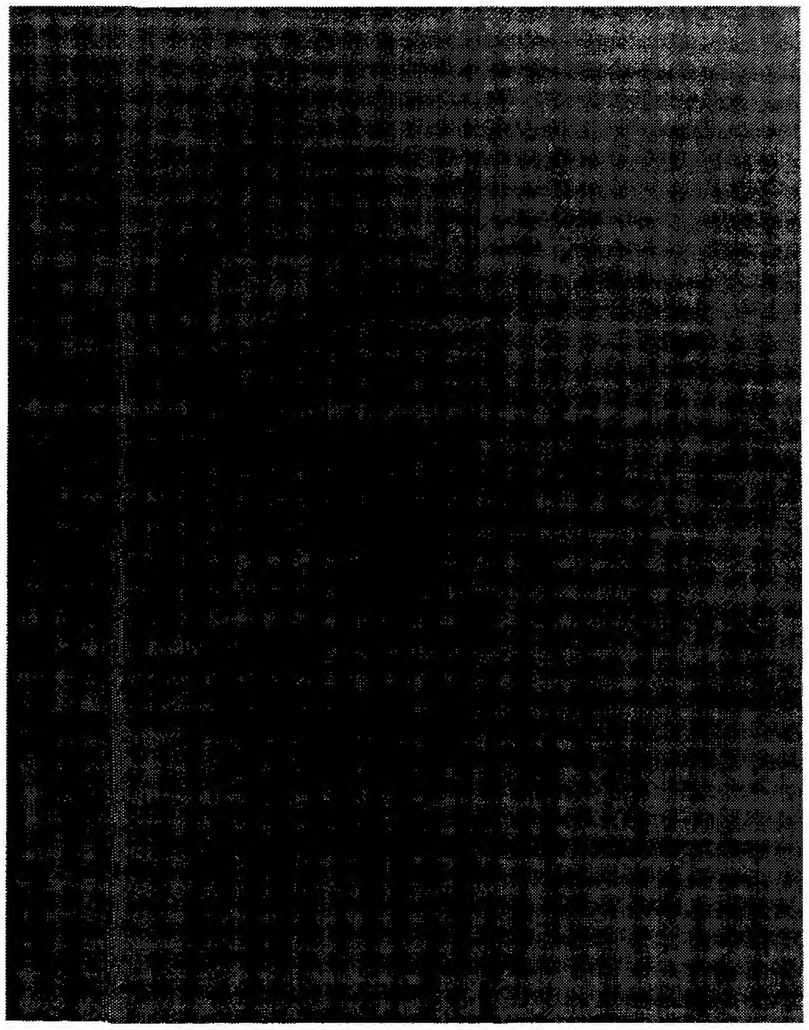
El Fondo Mundial De lucha contra el SIDA, la tuberculosis y la malaria · 全球基金 抗击艾滋病、结核和疟疾 · The Global Fund To Fight AIDS, Tuberculosis and Malaria · Le Fonds mondial De lutte contre le SIDA, la tuberculose et le paludisme · Глобальный фонд · الصندوق العالمي لمكافحة الأيدز والسل والملاريا

The Global Fund PSM Policy and Principles

- Procurement activities are the responsibility of the Recipient
- Global Fund policies aim to ensure that the Recipient is able to select :
  - among quality assured products (monthly list),
  - at the lowest possible price,
  - in the most adequate formulation (FDCs, children,..)
- Transparent, fair and competitive procurement
- Value for money
- Review of PSM plan and Price & Quality Reporting system



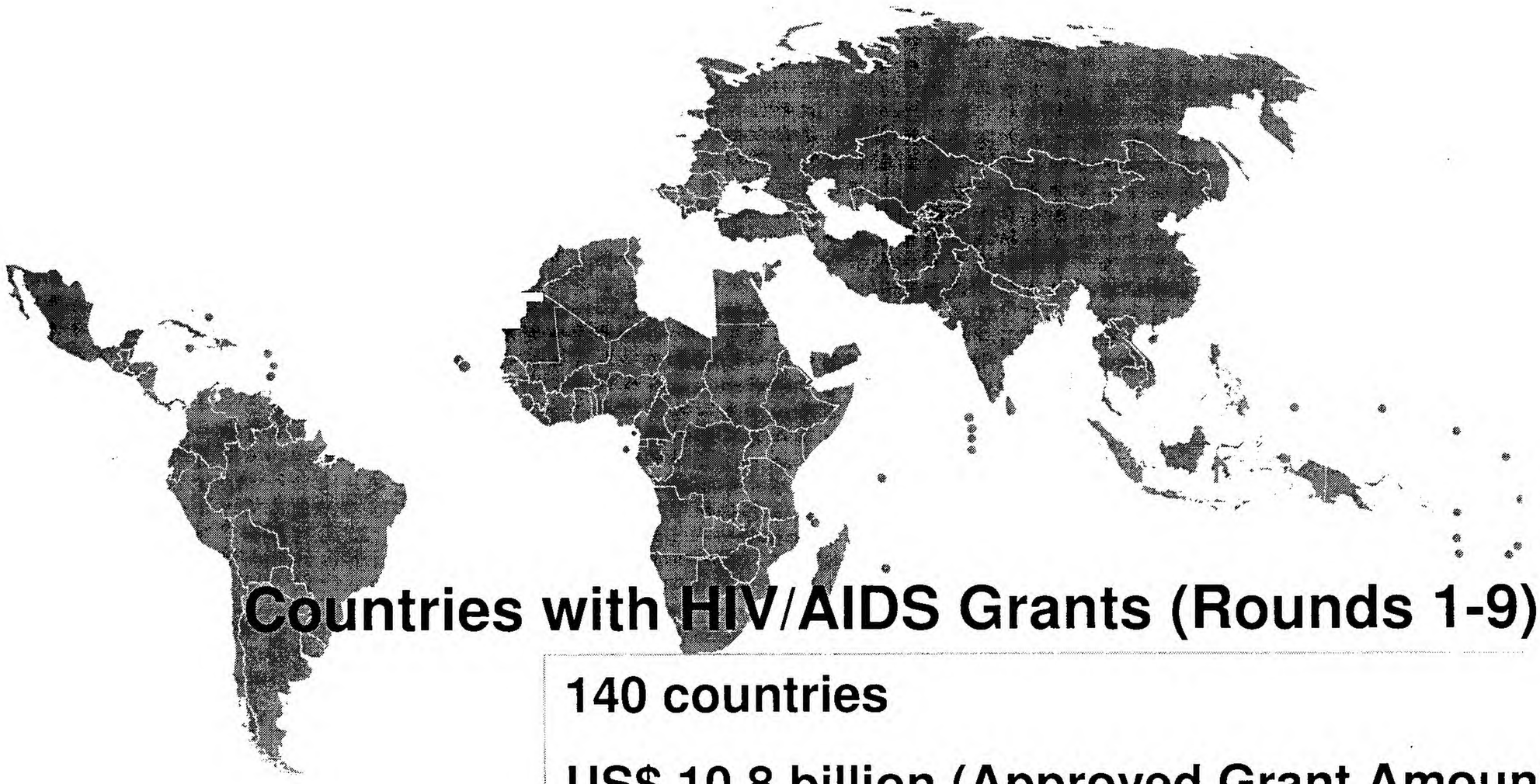
National and International Laws



Recipients must procure their products in accordance with national and international laws. The Global Fund encourages recipients to apply the flexibilities provided within national laws and in the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), as interpreted in the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), to achieve the lowest possible price for products of assured quality.

In the event that a Principal Recipient does not have the requisite capacity to assess the national and international intellectual property rights issues that apply to the desired products in their country, it may contract the necessary expertise using funds budgeted for this purpose in the Global Fund grant.

Global Fund HIV Financing



Countries with HIV/AIDS Grants (Rounds 1-9)

140 countries

US$ 10.8 billion (Approved Grant Amount)

US$ 17.4 billion (Total Lifetime Budget)

0 2,500 5,000
Kilometers

El Fondo Mundial
De lucha contra el SIDA, la tuberculosis y la malaria

全球基金
抗击艾滋病、结核和疟疾

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

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Глобальный фонд
لمكافحة الأيدز والسل والملاريا الصندوق العالمي

OP/140709/2

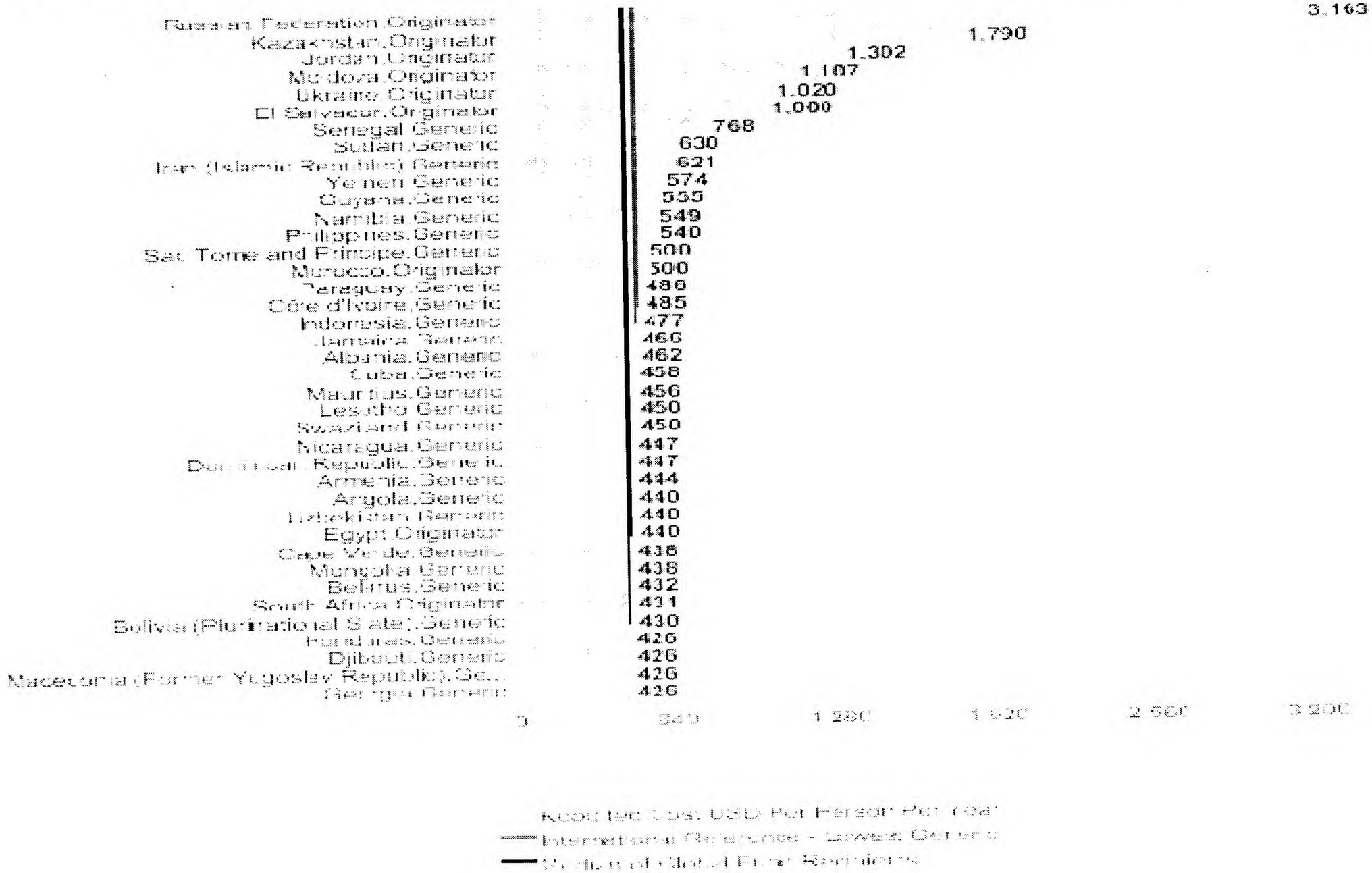
Global Fund Financing

Wide spectrum of countries among grantees:

- Unequal access to differential price programs of pharmaceutical companies;
- Different level of patent protection and TRIPS implementation;
- Bilateral and regional trade agreements;
- Unequal level of knowledge in IP.

Price differences across grantees: examples

Lopinavir (LPV)/Ritonavir (RTV), 200/50mg
Prices paid per year/patient in middle-income countries- since July 2009

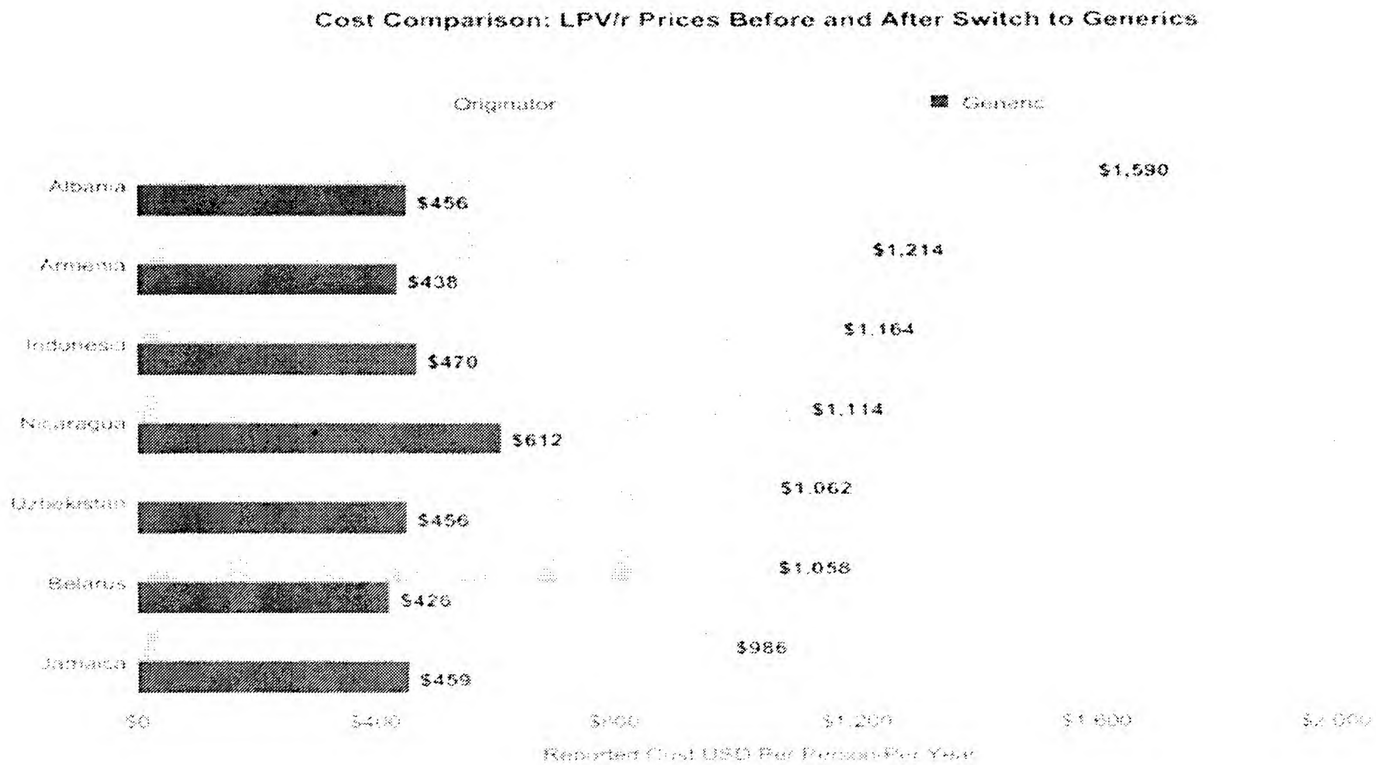


Price differences across grantees/2

- Patent barriers affect some countries' capacity to :
  - Procure lower priced versions of ARVs
  - Procure improved formulations (FDCs or children solid formulations) when they only exist as generics
    - eg.3TC in China
- Among Global Fund grants, affected countries are middle-income countries outside Sub-saharan Africa
  - Where patents for pharmaceutical products exist for key products
  - Excluded from discounts from patent holders or eligible only to second level of discount

Price differences among grantees/3

- Some of these countries are making substantial savings in grant budget by shifting to generic products (2009/2010)
  - In some cases after implementation of TRIPS flexibilities (governmental use-type licenses)



Management of patent issues in procurement cycle/1

- Procurement bottlenecks are common among grantees
  - weakness in forecasting, lack of capacity in PSM, problems on storage and distribution, etc

- Management of intellectual property issues is also a **procurement bottleneck**, further delaying the process
  - PSM plans (including estimated prices) are usually prepared without taking into account patent issues
  - Problems arise only late in the cycle, when procurement should actually start
  - Searching information, clarifications, etc. creates long delays
  - This leads to emergency procurement to avoid treatment disruption/stocks outs

Management of patent issues in procurement cycle/2

- Information about patents (and patent law) is not readily available.
- Delays on clarifying situation and potential options for the countries due to:
  - Disconnection between Ministry of Health and other authorities (trade, industry..)
  - Confusion with registration of medicines
  - Lack expertise of Procurement offices in countries

- Technical assistance possible with Global Fund grants but not very often requested

Management of patent issues in procurement cycle/3

- **Procurement agents** used by grantees:
  - In some cases, responsibility placed at country level for compliance with national law
    - acceptance of governmental use licenses
  - Or, request for patent status for all products in the order
  - Generally, limited patent search:
    - difficulties faced on doing patent search and very resource demanding
    - responsibility for verifying information placed at country level

In any case, time limit assessment to avoid stocks outs

Availability and quality of information

- Information about patent status often available only from the originator company (*letters*)
- If no information, or when information available from originator and other available information are not coincident ➔ *Chilling* effect
  - procurement agent unwilling to take risks (e.g. China lamivudine)
  - generic companies refusal to quote (e.g. Guatemala)
  - Pressure of time
  - And eventually procurement of higher priced products

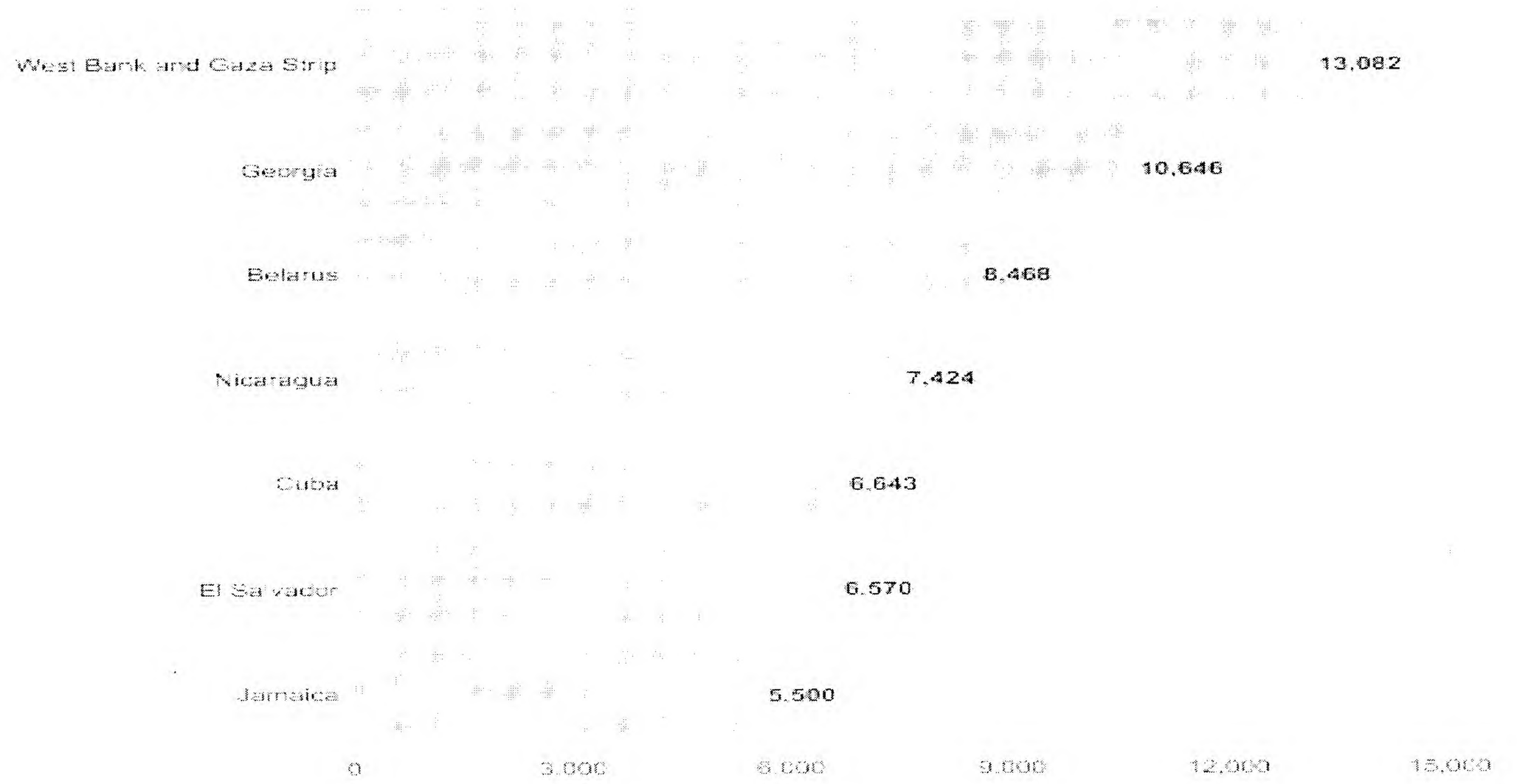
Availability and quality of information

- Validity of searches conducted at country level?
  - In many cases, search in local patent office done only using product name (INN) and formulation details.

    E.g. Key search word: Atazanavir 300 mg tablets.
  - With secondary patents, on new forms, combinations, .. How to ensure all possible patents are covered in search? (e.g. syrups)
  - Need for further guidance to patent offices on moving forward (new ARVs, increase in secondary patent applications)

More recent ARVs

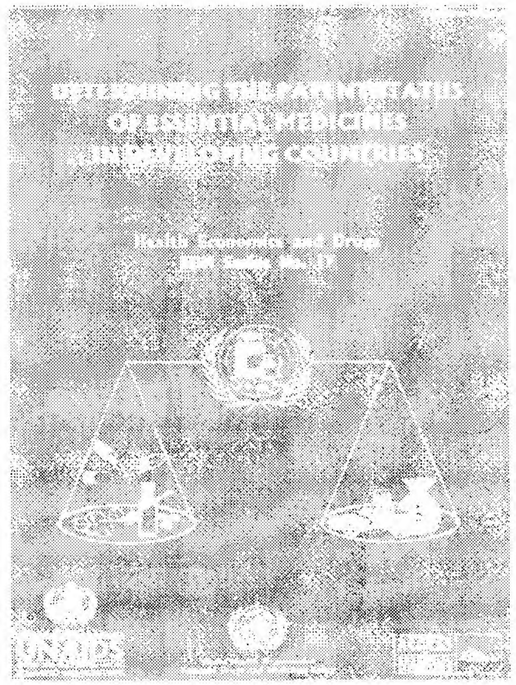
Darunavir prices paid per year/patient by all Recipients

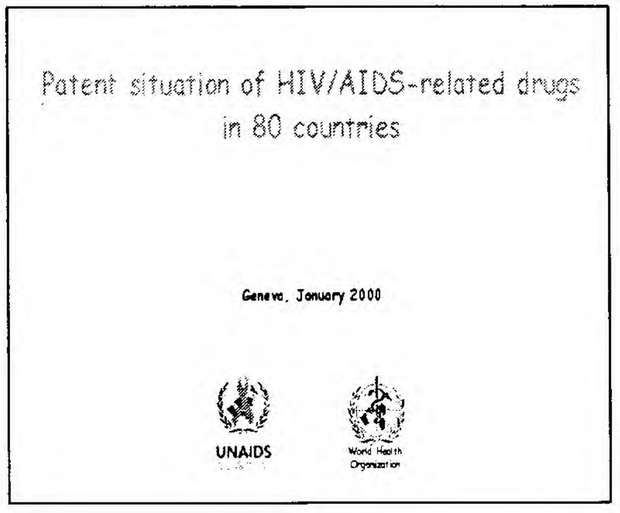


1,095$ offered by patent holder to Sub-Saharan Africa and LDCs

What patent information could be useful for facilitating procurement process?

- Public list of basic and secondary patents of key products and formulations
  - date and numbers
  - E.g. UNAIDS/MSF/WHO 2004
- On-line data-base or consultation service
  - Specifically important now for middle income countries
  - E.g. WIPO





Guidance and simplified tools

- Guidance for developing capacity at country level:
  E.g. WHO 2010, UNDP

- Once patent status known, in some cases ➔ will need Technical Assistance to determine options for procurement of lower-priced generics

- Need for simplified solutions for managing IP rights upfront ➔ Medicines Patent Pool